DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-733/S-012

Sanofi-Synthelabo
90 Park Avenue
New York, NY 10016

Attention: Thomas M. Conroy Jr., RPh, JD
Regulatory Affairs Manager

Dear Mr. Conroy:

Please refer to your supplemental new drug application dated August 22, 2002, received August 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Talwin NX® (pentazocine HCl and naloxone HCl) Tablets.

This supplemental new drug application provides for a revised **PRECAUTIONS** section of the package insert. A "**Geriatric Use**" subsection is added in accordance with the requirements of 21 CFR 201.57 (f)(10)(ii)(A).

We have completed our review of this application and it is approved, effective on the date of this letter, with the minor editorial revisions listed below.

1. Revise the last sentence of the *Geriatric Use* subsection as follows:
   In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy."

2. Revise the **HOW SUPPLIED** section of the package insert and container label with a storage statement, "Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted August 22, 2002). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-733/S-012." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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